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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,188	03/20/2001	Gunther Sawatzki	REF/SAWATZKI	3636

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EXAMINER

OH, SIMON J

ART UNIT PAPER NUMBER

1618

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/774,188

Applicant(s)

SAWATZKI ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 14-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's amendment and response, both received on 16 March 2004.

### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 15, 16, 22-26, 31 and 32 under 35 U.S.C. 112, second paragraph is hereby withdrawn.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 14-32 under 35 U.S.C. 103(a) over Green et al. in view of Paul is maintained.

Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. in view of Paul.

The Green et al. patent teaches a nutritional composition composed of oligosaccharides such as galacto-oligosaccharides and fructo-oligosaccharides, present in the amount of 8% to

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70% (See Column 2, Line 4). Oligosaccharides are understood to comprise any saccharide containing at least two and up to 20 monosaccharide units. Especially preferred are oligosaccharides having an average chain length of between 3 and 9 monosaccharide units (See Column 3, Lines 1-16). Regarding component B, the disclosed composition further contains soluble non-starch polysaccharides that include components such as inulin, beta glucans, pectin, xanthan, carageenans and alginates (See Column Lines 2 and 47-59). This component is present in the amount of 15% to 50% by weight. Examples of insoluble non-starch polysaccharide include cellulose and hemicellulose, present in the range of 15% to 45 % by weight (See Column 2, Lines 3 and 60-67). The disclosed compositions may further comprise starches, preferably at levels ranging from 5% to 30% by weight (See Column 3, Lines 23-35).

The nutritional composition disclosed by Green will further contain digestible carbohydrates that may include monosaccharides, disaccharides and digestible oligosaccharides and polysaccharides (See Column 4, Lines 24-30). It has been shown that administration of fructo-oligosaccharides (FOS) enhances growth of the bifidobacteria population in the intestine, suppresses production of putrefactive factors, improves blood lipid levels in hyperlipidemia patients and provides relief from constipation (See Paul, Column 7, Lines 16-24). Other claim limitations not explicitly disclosed by the prior art are considered implicitly disclosed by the prior art, as a composition cannot be held apart from its properties. Paul is cited to support this position. Concentrations specifically recited by the applicant are not considered to be patentable above the prior art, as the prior art compositions and the instantly claimed invention are used for same intended purpose. Obtaining such concentrations are considered by the examiner to be well within the purview of one of ordinary skill in the art in the course of routine experimentation and

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optimization. Absent a showing of some unexpected result, the claims are considered to be prima facie obvious.

### ***Response to Arguments***

Applicant's arguments filed 16 March 2004 have been fully considered but they are not persuasive. The examiner does not consider the phrase "consists of" to render patentability above the prior art. The prior art compositions and the instantly claimed invention are used for the same purpose, and the applicant has not shown why the inclusion of only the two components and an optional third component is patentable over the broad disclosure of the prior art. The examiner shifts the burden onto the applicant to show that the additional ingredients disclosed in the prior art are detrimental to the function of the instantly claimed invention.

Applicant's arguments appear to be primarily grounded solely within the functional language of the claims. So long as the instant invention is defined only by claim language that recites features of particular components and/or the functions of particular components, in the view of the examiner, such broad claim language invites the application of broad prior art against the instant claims. The instant specification appears deficient as to why certain recited claim limitations are essential to the instantly claimed invention. Why is it so important that components A and B do not have glucose units linked at the  $\alpha$  1-4 or  $\alpha$  1-6 position? The instant specification only mentions in broad terms that it might have a biochemical or physiological influence on the effectiveness of the instantly claimed invention, but no specifics are given, nor are any sort of conclusive data that demonstrate this feature as being critical. That the entire list of pending claims does not recite even a single species or even a genus that embodies the

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limitations and functional language ascribed to components A or B permits the examiner to place a prior art rejection on the instant claims that is as broad as the claims themselves.

The examiner would therefore like to point out to the applicant that the instant application will be in better condition towards allowance with the recitation of specific components, or with conclusive data showing the unexpected results that arise from the recited limitations, such as but not necessarily limited to the number of monosaccharide units, the difference in structure and size between the two components, and the absence of glucose units linked at the  $\alpha$  1-4 or  $\alpha$  1-6 position for both components. All claims will remain rejected.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh  
Examiner  
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sj0

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